REMARKS

Claims 8-15, 17-18, 38-58, and 62-70 are pending, with claims 8, 14, 46, 62, 67, and 68 being independent. Claims 42-43, 51, and 53 have been withdrawn by the Examiner. Claims 8, 14, 46, 62, 67, and 68 have been amended, and new claims 69-70 have been added. Support for the amendments and the new claims can be found in the originally-filed specification, for example, at page 13, lines 2-26 and page 17, lines 18-30. No new matter has been introduced.

Claim Rejections Under 35 U.S.C. § 112

Claims 40, 46, 50, 62, 64, and 68 stand rejected under the first paragraph of 35 U.S.C. § 112 for allegedly failing to comply with the written description requirement. Specifically, the Examiner contends that Applicants' disclosure does not sufficiently describe the input of response data features of claims 40, 46, 50, 62, 64, and 68.

When a disclosure describes a claimed invention in a manner that permits one skilled in the art to reasonably conclude that the inventor possessed the claimed invention, the written description requirement is satisfied. MPEP §2163. This possession may be shown in any number of ways and an Applicant need not describe every claim feature exactly because there is no *in haec verba* requirement. Id. Rather, to satisfy the written description requirement, all that is required is "reasonable clarity." MPEP § 2163.02.

According to the Examiner, the Applicants do not have possession of inputting the level of concordance/non-concordance of the pain via the sliding device, as recited in claims 40, 50, and 64, because although the sliding device possesses an axis for relating level of concordance/non-concordance of the pain, there is "no disclosure of a second sliding scale."[1] Office action at 3. The claims, however, do not require a "second sliding scale" for input of the concordance/non-concordance response data. The claims recite that the pain level and

[1] The Examiner also asserts that independent claims 46, 62, and 68 recite that the pain level and concordance response data are inputted separately using a sliding device. However, these claims do not recite a sliding device. Claims 46 and 68 recite that the data are inputted separately by hand and claim 62 recites that the data are inputted separately. For at least these reasons, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 46, 62, and 68. If the Examiner is unwilling to withdraw the rejections, Applicants request further clarification of the Examiner's rejections so that Applicants may properly respond thereto.

concordance response data are inputted separately by hand by the patient using the sliding device and that the sliding device is correlated to a visual analog scale (VAS) from 0-10 and includes an axis for relating level of concordance, non-concordance, or concordance and non-concordance of the pain. Moreover, it is unclear how the Examiner asserts that the "Applicant does not have possession of the subject matter that the axis relates level of concordance, non-concordance of the pain," (Office action at 4), when the specification expressly describes such features. See, e.g., application at 17, lines 22-24.

Applicants submit that one of ordinary skill in the art would reasonably conclude that Applicants' disclosure adequately described the claimed invention at the time of filing at least because a review of the present application reveals that Applicants describe using a sliding device correlated to a visual analog scale (e.g., for entering pain level response data) and including an axis for separately inputting level of concordance/non-concordance of the pain. (See, e.g., application at 17, lines 19-26). Those of ordinary skill in the art would understand that such a disclosure describes, either implicitly or expressly, separately inputting pain level and concordance data using a sliding device.

Applicants thus respectfully requests favorable reconsideration and withdrawal of the rejections under 35 U.S.C. § 112.

Claim Rejections Under 35 U.S.C. 102

The Examiner has rejected claims 8-13, 41, 44-45, and 67 as anticipated by U.S. Patent No. 6,370,420 to Kraft ("Kraft"). Claims 8 and 67 are independent.

Independent claims 8 and 67, as amended, recite a computer readable medium having code that, when executed by a computer, receives three types of data: (i) fluid introduction data; (ii) response data indicative of pain level of a response; and (iii) response data, input separately from pain level data, indicative of whether the pain level response of the patient is a result of a pain symptom or is a result of pain unrelated to the pain symptom. As implicitly recognized by the Examiner in the Office action (see action at 11), Kraft fails to disclose or suggest these features.

Accordingly, claims 8 and 67 are allowable over Kraft, as are dependent claims 9-13, 41, and 44-45.[2]

The Examiner has rejected claims 14-15, 17-18, and 55-58 as anticipated by U.S. Patent No. 6,945,954 to Hochman et al. ("Hochman"). Claim 14 is independent.

Independent claim 14 recites an operator configured to actuate the introducer, the operator including code to empirically determine impedance data indicative of the flow rate-dependent impedance based upon a determination of pressure and volume of fluid dispensed during an actuation of the introducer prior to insertion of the introducer into the spine. Hochman fails to disclose or suggest these claimed features. In contrast, as the Examiner recognizes, the determination of impedance data in Hochman occurs as one or more system characteristics are entered by the physician and retrieved from the database." Office action at 10.

Accordingly, claim 14 is allowable over Hochman, as are dependent claims 15, 17-18, and 55-58.

Claim Rejections Under 35 U.S.C. 103

The Examiner has rejected claim 38, which depends from claim 8, as being obvious over Kraft in view of U.S. Patent No. 6,258,042 to Factor et al. ("Factor"). Factor does not overcome the deficiencies in Kraft discussed above. In particular, Factor fails to disclose or suggest concordance response data, input separately from pain level data, indicating whether the pain level response of the patient is a result of a pain symptom or is a result of pain unrelated to the pain symptom. The sliding device of Factor, at best, only provides an indication of the patient's pain level at the time of fluid introduction. For at least these reasons, claim 38 is patentable over Kraft in view of Factor.

The Examiner has rejected claims 38-40, 46-50, 52-54, 62-66, and 68 as being obvious over Kraft in view of U.S. Patent No. 5,692,500 to Gaston-Johansson ("Gaston-Johansson"). Gaston-Johansson does not overcome the deficiencies in Kraft discussed above. In particular, Gaston-Johansson does not disclose or suggest receiving response data indicative of pain level of

[2] New claims 69 and 70, which depend from claims 8 and 67, respectively, are allowable for at least the same reasons.

a response of the patient at a time related to a time of the fluid introduction data, and response data, input separately from the pain level data, indicative of concordance of the response of the patient at the time related to the time of the fluid introduction data, the concordance data indicating whether the pain level response of the patient is a result of a pain symptom or is a result of pain unrelated to the pain symptom. Instead, scale 66, which the Examiner equates with the mechanism used for the input of concordance data, is used for the input of the relevant extent of the duration of the pain symptoms. For at least these reasons, claims 38-40, 46-50, 52-54, 62-66, and 68 are patentable over Kraft in view of Gaston-Johansson.

The Examiner has rejected claims 38-40, 46-50, 52-54, 62-66, and 68 as being obvious over Kraft in view of U.S. Patent No. 6,856,315 to Eberlein ("Eberlein"). Eberlein likewise does not overcome the deficiencies in Kraft discussed above. In particular, Eberlein does not disclose or suggest receiving response data indicative of pain level of a response of the patient at a time related to a time of the fluid introduction data, and response data, input separately from the pain level data, indicative of concordance of the response of the patient at the time related to the time of the fluid introduction data, the concordance data indicating whether the pain level response of the patient is a result of a pain symptom or is a result of pain unrelated to the pain symptom. Rather, body map diagram 420, which the Examiner equates with the mechanism used for the input of concordance data, allows a user to graphically indicate one or more areas on the body map 420 in which the user is experiencing pain. Nowhere does Eberlein disclose or suggest that this information may provide concordance information as claimed. For at least these reasons, claims 38-40, 46-50, 52-54, 62-66, and 68 are patentable over Kraft in view of Eberlein.

Applicants do not acquiesce in the Examiner's characterizations of the art. For brevity and to advance prosecution, applicants may not have addressed all characterizations of the art and reserve the right to do so in further prosecution of this or a subsequent application. The absence of an explicit response by applicants to any of the Examiner's positions does not constitute a concession of the Examiner's positions. The fact that applicants' comments have focused on particular arguments does not constitute a concession that there are not other

arguments for patentability of the claims. Applicants submit that all of the dependent claims are patentable for at least the reasons given with respect to the claims on which they depend.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

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